NOV 2 4 2003

510(k) Summary

K033548

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett

Date Prepared: November 11, 2003

2) Device name

Proprietary name: Roche Diagnostics Urisys 1100™ Urine Analyzer
Common name: Automated Urinalysis System
Classification name: Automated Urinalysis System

3) Predicate device

The Urisys 1100 Urine Analyzer is substantially equivalent to the current legally marketed Chemstrip 101 Urine Analyzer. Chemstrip 101 Urine Analyzer was originally cleared for use with the Chemstrip 10 UA test strips under K983510. The Chemstrip 10 MD, Chemstrip 7 and Chemstrip 5 OB test strips were cleared on the Chemstrip 101 Urine Analyzer under K032437.

4) Device Description

The Urisys 1100 Urine Analyzer is a modification of the previously cleared Chemstrip 101.

5) Intended use

The Urisys 1100 Urine Analyzer is a reflectance photometer designed to automatically read and evaluate the results of Chemstrip 5 OB, Chemstrip 7 and Chemstrip 10 MD urine test strips for various urine analytes: specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood.

6) Similarities	The table below indicates the similarities between the Urisys 1100 and Chemstrip 101 Urine Analyzers.

Feature/Claim	Urisys 1100 Urine Analyzer	Chemstrip 101 Urine Analyzer
Intended Use	Reflectance photometer designed to automatically read and evaluate the results of Chemstrip 10 MD, Chemstrip 7 and Chemstrip 5 OB	Same
Fundamental Technology	Reflectance Photometer	Same
Test Parameters	Specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood	Same
User Interface	To perform a test, simply dip the test strip in the urine sample, gently press the long edge of the test strip to a piece of absorbent paper for one second, and place it in the test strip tray with the pads facing upward. Then, press the START button. Measurement is complete in 70 seconds, and results are automatically printed.	Same

7) Modifications	The following table lists the modified features of the Urisys 1100 Urine Analyzer.

Feature/Claim	Description
Housing	The external housing was made smaller to give it a more modern design look.
Printer	A new integrated, fast and silent thermal printer with automatic paper feed is being introduced with the Urisys 1100.
Transport	The test strip transport has been improved by incorporating a new cog wheel drive and improved test strip tray.
LED	The measurement head will still contain 6 LEDs, and the LEDs (green and orange) used for measurement purposes will not change. However, the red LED, which is not used as part of the measurement function, is being replaced with a more common LED.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

NOV 2 4 2003

Re: k033548
Trade/Device Name: Urisys 1100 Urine Analyzer
Regulation Number: 21 CFR § 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: II
Product Code: JIL, KHE, KQO
Dated: November 11, 2003
Received: November 12, 2003

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K03 3548 Special

Device Name: Urisys 1100 Urine Analyzer

Indications for Use:

The Urisys 1100 Urine Analyzer is a reflectance photometer designed to automatically read and evaluate the results of Chemstrip 5 OB, Chemstrip 7 and Chemstrip 10 MD urine test strips for various urine analytes: specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K03 3548 "Special"

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)